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A-72018

Attorney Docket No.: 014643-012110US
A-72018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

TOMIZUKA et al.

Serial No. 10/000,433

Filing Date: November 30, 2001

For: *Transgenic Transchromosomal
Rodents for Making Human
Antibodies*

Examiner: LI, Q. Janice

Group Art Unit: 1632

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

Dated: May 6, 2003

Signed: *Jere Valles*
Jere Valles

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. Copies of the references are enclosed.

Further, in accordance with the provisions of 37 C.F.R. §§ 1.97(c) and 1.97(e)(1), the undersigned certifies that references A13, C87, and C94, listed on the enclosed form PTO/SB/8A, were first cited in the International Search Report dated February 6, 2003, for a counterpart PCT application. As such, the filing of the instant Information Disclosure Statement is within three months of the date of that International Search Report and, therefore, need not be

Serial No. 10/000,433

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accompanied by the fee as set forth in 37 C.F.R. § 1.17(p). A copy of the International Search Report for the counterpart PCT application is enclosed herewith.

None of the foregoing references are believed to disclose the invention as claimed. Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. Although no fee is believed to be due, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 455675-00083 (A-72018/GKS/THR)).

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: 06 May 2003
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Attachments : Form PTO/SB/8A
Copies of references cited on Form PTO/SB/8A
International Search Report for PCT/US01/45293



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Substitute for form 1449A/PTO
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 7

Complete if Known

Application Number	10/000,433
Filing Date	November 30, 2001
First Named Inventor	TOMIZUKA, Kazuma
Group Art Unit	
Examiner Name	
Attorney Docket Number	014643-012110US (A-72018/455675-83)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,175,384	12-1992	Krimpenfort	
	A2	5,204,244	04-1993	Fell et al.	
	A3	5,416,260	05-1995	Jikker	
	A4	5,434,340	07-1995	Krimpenfort	
	A5	5,545,806	08-1996	Lonberg et al.	
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	B1	EP 0 315 062 ✓	05-1989			
	B2	WO 90/04036 ✓	04-1990			
	B3	WO 90/12878 ✓	11-1990			
	B4	WO 91/00906 ✓	01-1991			
	B5	WO 91/10741 ✓	07-1991			
	B6	WO 92/03918 ✓	03-1992			
	B7	WO 96/02576 ✓	02-1996			

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				Attorney Docket Number	014643-012110US (A-72018/455675-83)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	†
✓	C59	NUSSENZWEIG, M.C., et al., "A human immunoglobulin gene reduces the incidence of lymphomas in c-Myc-bearing transgenic mice", <i>Nature</i> 336:446-450 (1988).	
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Examiner Signature	Date Considered
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			Application Number	10/000,433	
			Filing Date	November 30, 2001	
			First Named Inventor	TOMIZUKA, Kazuma	
			Group Art Unit		
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				Attorney Docket Number	014643-012110US (A-72018/455675-83)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
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✓	C44	LORENZ, W., et al., "Physical map of the human immunoglobulin κ locus and its implications for the mechanisms of V_{κ} - J_{κ} rearrangement", <i>Nucl. Acids Res.</i> 15:9667-9676 (1987).		
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✓	C50	MORRISON, S.L., "Success in specification", <i>Nature</i> 368:812-813 (1994).		
✓	C51	MOWATT, M.R., et al., "DNA sequence of the murine $\gamma 1$ switch segment reveals novel structural elements", <i>J. Immunol.</i> 136:2674-2683 (1986).		
✓	C52	MÜLLER, W., et al., "Membrane-bound IgM obstructs B cell development in transgenic mice", <i>Eur. J. Immunol.</i> 19:923-928 (1989).		
✓	C53	MURRAY, A.W., and SZOSTAK, J.W., "Construction of artificial chromosomes in yeast", <i>Nature</i> 305:189-193 (1983).		
✓	C54	NIKAIDO, T., et al., "Nucleotide Sequences of Switch Regions of Immunoglobulin C and C Genes and Their Comparison", <i>J. Biol. Chem.</i> 257:7322-7239 (1982).		
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✓	C56	NEUBERGER, M.S., et al., "Isotype exclusion and transgene down-regulation in immunoglobulin- λ transgenic mice", <i>Nature</i> 338:350-352 (1989).		
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✓	C58	NUSSENZWEIG, M.C., et al., "Allelic exclusion in transgenic mice carrying mutant human IgM genes", <i>J. Exp. Med.</i> 167:1969 (1988).		

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
✓	C20	FISHWILD, D.M., et al., "High-Avidity human IgGκ monoclonal antibodies from a novel strain of minilocus transgenic mice", <i>Nature Biotechnology</i> 14:845. (1996).
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✓	C22	GERSTEIN, R.M., et al., "Isotype Switching of an Immunoglobulin Heavy Chain Transgene Occurs by DNA Recombination between Different Chromosomes", <i>Cell</i> 63:537-548 (1990).
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✓	C25	GREEN, L.L., et al., "Antigen-specific human monoclonal antibodies from mice engineered with human Ig heavy and light chain YACs", <i>Nature Genetics</i> 7:13-21 (1994).
✓	C26	HAGMAN, J., et al., "Inhibition of immunoglobulin gene rearrangement by the expression of a $\lambda 2$ transgene", <i>J. Exp. Med.</i> 169:1911-1929 (1989).
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✓	C31	IGLESIAS, A., et al., "Expression of immunoglobulin delta chain causes allelic exclusion in transgenic mice", <i>Nature</i> 330:482-484 (1987).
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✓	C36	JUNG, S., et al., "Shutdown of Class Switching Recombination by Deletion of a Switch Region Control Element", <i>Science</i> 259:984-987 (1993).
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✓	C1	ALT, F.W., et al., "Immunoglobulin genes in transgenic mice", <i>Trends in Genetics</i> , 231-236, (Aug. 1985).	
✓	C2	BERMAN, J.E., et. al., "Content and organization of the human Ig V _H locus: definition of three new V _H families and linkage to the Ig C _H locus", <i>The EMBO J.</i> 7:727-738 (1988).	
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✓	C9	CAPECCHI, M.R., "Altering the genome by homologous recombination", <i>Science</i> 244:1288-1292 (1989).	
✓	C10	CAPECCHI, M.R., "The new mouse genetics: Altering the genome by gene targeting", <i>Trends in Genetics</i> 5:70-76 (1989).	
✓	C11	CHOI, T.K., et al., "Transgenic mice containing a human heavy chain immunoglobulin gene fragment cloned in a yeast artificial chromosome." <i>Nat Genet.</i> 1993 Jun;4(2):117-23.	
✓	C12	COFFMAN, R.L., et al., "A mouse T cell product that preferentially enhances IgA production", <i>J. Immunol.</i> 139:3685-3690 (1987).	
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✓	C14	DAVIES, N.P., et al., "Creation of Mice Expressing Human Antibody Light Chains by Introduction of a Yeast Artificial Chromosome Containing the Core Region of the Human Immunoglobulin κ Locus." <i>Biotechnology (N Y)</i> . 1993 Aug;11(8):911-4.	
✓	C15	DAVIES, N.P., et al., "Targeted Alterations in Yeast Artificial Chromosomes for Inter-Species Gene Transfer", <i>Nucleic Acid Res.</i> 20: 2693-2698 (1992).	
✓	C16	DOETSCHMAN, T., et al., "Targetted correction of a mutant HPRT gene in mouse embryonic stem cells", <i>Nature</i> 330:576-578 (1987).	
✓	C17	DURDIK, J., et al., "Isotype switching by a microinjected μ immunoglobulin heavy chain gene in transgenic mice", <i>Proc. Natl. Acad. Sci. USA</i> 86:2346-2350 (1989).	
✓	C18	ESSER, C., and RADBRUCH, A., "Rapid induction of transcription of unrearranged S γ 1 switch regions in activated murine B cells by interleukin 4", <i>The EMBO J.</i> 8:483-488 (1989).	
✓	C19	FERRIER, P., et al., "Separate elements control DJ and VDJ rearrangement in a transgenic recombination substrate", <i>The EMBO J.</i> 9:117-125 (1990).	

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				Application Number	10/000,433
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	November 30, 2001
				First Named Inventor	TOMIZUKA, Kazuma
				Group Art Unit	
				Examiner Name	
(use as many sheets as necessary)				Attorney Docket Number	014643-012110US (A-72018/455675-83)
Sheet	6	of	7		

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Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	†
✓	C79	SMITHIES, O., et al., "Insertion of DNA sequences into the human chromosomal β -globin locus by homologous recombination", <i>Nature</i> 317:230-234 (1985).	
✓	C80	SNAPPER, C.M., and Paul, W.E., "Interferon- γ and B Cell Stimulatory Factor-1 Reciprocally Regulate Ig Isotype Production", <i>Science</i> 236:944-947 (1987).	
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✓	C82	STAVNEZER, J., et al., "Immunoglobulin heavy-chain switching may be directed by prior induction of transcripts from constant-region genes", <i>Proc. Natl. Acad. Sci. (U.S.A.)</i> 85:7704-7708 (1988).	
✓	C83	STORB, U., et al., "Expression, Allelic Exclusion and Somatic Mutation of Mouse Immunoglobulin Kappa Genes", <i>Immunological Reviews</i> 89:85-102 (1986).	
✓	C84	STORB, U., "Immunoglobulin Gene Analysis in Transgenic Mice, in <i>Immunoglobulin Genes</i> , Academic Press Limited, pp. 303-326 (1989).	
✓	C85	SZUREK, P., et al., "Complete nucleotide sequence of the murine γ 3 switch region and analysis of switch recombination in two γ 3-expressing hybridomas", <i>J. Immunol.</i> 135:620-626 (1985).	
✓	C86	TAHARA, T., et al., "HLA antibody responses in HLA class I transgenic mice", <i>Immunogenetics</i> 32:351-360 (1990).	
✓	C87	TAKAI, T., et al., "Augmented Humoral and Anaphylactic Responses in Fc γ RII-deficient Mice", <i>Nature</i> 379:346-349 (1996).	
✓	C88	TAKI, S., et al., "Targeted Insertion of a Variable Region Gene into the Immunoglobulin Heavy Chain Locus", <i>Science</i> 262:1268-1271 (1993).	
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✓	C91	TAYLOR, L.D., et al., "Human immunoglobulin transgenes undergo rearrangement, somatic mutation and class switching in mice that lack endogenous IgM", <i>International Immunology</i> 6:579-591 (1994).	
✓	C92	THOMAS, K.R., and CAPECCHI, M.R., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells", <i>Cell</i> 51:503-512 (1987).	
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✓	C94	TOMIZUKA, K., et al., "Double Trans-Chromosomal Mice: Maintenance of Two Individual Human Chromosome Fragments Containing Ig Heavy and Kappa Loci and Expression of Fully Human Antibodies," <i>Proc. Nat. Acad. Sci (USA)</i> 97:722-727 (2000)	
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✓	C97	WAGNER, S.D., et al., "Antibodies generated from human immunoglobulin miniloci in transgenic mice." <i>Nucleic Acids Res.</i> 1994 Apr 25;22(8):1389-93.	

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✓	C98	WEAVER, D., et al., "A Transgenic Immunoglobulin Mu Gene Prevents Rearrangement of Endogenous Genes", <i>Cell</i> 42:117-127 (1985).	
✓	C99	WEISS, R., "Mice Making Human-Like Antibodies", <i>The Washington Post</i> , Apr. 28, 1994.	
✓	C100	YAMAMURA, K.-I., et al., "Cell-type-specific and regulated expression of a human $\gamma 1$ heavy-chain immunoglobulin gene in transgenic mice", <i>Proc. Natl. Acad. Sci. USA</i> 83:2152-2156 (1986).	
✓	C101	YANCOPOULOS, G.D., and ALT, F.W., "Developmentally Controlled and Tissue-Specific Expression of Unrearranged V _H gene segments", <i>Cell</i> 40:271-281 (1985).	
✓	C102	YANCOPOULOS, G.D., and ALT, F.W., "Regulation of the Assembly and Expression of Variable-Region Genes", <i>Ann. Rev. Immunol.</i> 4:339-368 (1986).	
✓	C103	YASUI, H, et al., "Class switch from μ to δ is mediated by homologous recombination between σ_{μ} and Σ_{μ} sequences in human immunoglobulin gene loci", <i>Eur. J. Immunol.</i> 19:1399-1403 (1989).	
✓	C104	ZIJLSTRA, M., et al., "Germ-line transmission of a disrupted β_2 -microglobulin gene produced by homologous recombination in embryonic stem cells", <i>Nature</i> 342:435-438 (1989).	
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